

James S. Jardine (1647)  
jjardine@rqn.com  
Arthur B. Berger (6490)  
aberger@rqn.com  
Samuel C. Straight (7638)  
ssstraight@rqn.com  
RAY QUINNEY & NEBEKER P.C.  
36 South State Street, Suite 1400  
P. O. Box 45385  
Salt Lake City, Utah 84145-0385  
Telephone: (801) 532-1500  
Facsimile: (801) 532-7543

L. Scott Oliver (*pro hac vice*)  
Scott.Oliver@klgates.com  
Ranjini Acharya (*pro hac vice*)  
ranjini.acharya@klgates.com  
K&L GATES LLP  
630 Hansen Way  
Palo Alto, California 94304  
Telephone: (650) 798-6700  
Facsimile: (650) 798-6701

Attorneys for Defendant and Counterclaimant  
ATLANTIC PRO-NUTRIENTS, INC.,  
D/B/A XYMOGEN

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION**

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<p>THORNE RESEARCH, INC. and SOFTGEL FORMULATORS, INC.,</p> <p>Plaintiffs,</p> <p>vs.</p> <p>ATLANTIC PRO-NUTRIENTS, INC., d/b/a XYMOGEN,</p> <p>Defendant.</p>	<p>Case No. 2:13-cv-00784</p> <p><b>ATLANTIC PRO-NUTRIENTS, INC., D/B/A XYMOGEN'S OPENING CLAIM CONSTRUCTION BRIEF</b></p> <p>Assigned to Magistrate Judge Paul M. Warner</p>
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## **I. INTRODUCTION**

Thorne Research, Inc. and Softgel Formulators, Inc. (collectively “Thorne” or “Plaintiffs) have alleged that XYMOGEN f/k/a Atlantic Pro-Nutrients, Inc. (“XYMOGEN”) infringes U.S. Patent No. 8,491,888 (the “‘888 Patent”, copy attached as Ex. A). The parties initially identified 9 claim terms from the ’888 patent that needed construction. After meeting and conferring, the parties agreed to constructions of 7 terms. Exhibit B lists the terms on which the parties found agreement along with the agreed-to constructions. The remaining two terms on which the parties could not reach agreement are “carrier oil” and “non-crystalline.” XYMOGEN submits this opening claim construction brief in support of its proposed constructions of these terms.

## **II. SUMMARY OF THE ‘888 PATENT**

The ’888 Patent describes a nutraceutical formulation containing coenzyme Q10 (or CoQ10). CoQ10 is an antioxidant and has various reported health benefits, in particular for heart function. (Ex. A, 1:22-33) According to the ’888 Patent, formulations that existed at the time the ’888 Patent was filed were not well absorbed into the body because the crystalline form of CoQ10 is difficult for the body to adsorb, and oils used to dissolve CoQ10 were “undesirable solvent[s] and/or inhibit absorption.” (Ex. A, 1:33-46)

The ’888 Patent claims an allegedly new and improved formulation that contains CoQ10 in a completely crystal-free form along with a “solvent” and a “carrier oil.” (See, e.g., claim 1) The solvent is able to “completely dissolve” the CoQ10 crystals. (Ex. A, 4:14-15) After being completely dissolved, the CoQ10 exists in a crystal-free form. A carrier oil is added to improve the absorption level of CoQ10 into the blood of a person who ingests the crystal-free nutraceutical formulation. (Ex. A, 2:66-3:1) The carrier oil transports CoQ10 molecules across

the cells in the lining of the intestine, thereby allowing the CoQ10 to be absorbed into the bloodstream. (Ex. A, 3:1-9)

### **III. LEGAL STANDARDS**

It is a “bedrock principle” of patent law that the claims of a patent and not the examples set forth in the specification define the patented invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*). The purpose of claim construction is to “determin[e] the meaning and scope of the patent claims asserted to be infringed.” *O2 Micro Intern. Ltd. v. Beyond Innovation Technology Co., Ltd.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008). “When the parties raise an actual dispute regarding the proper scope of these claims, the court, not the jury, must resolve that dispute.” *Id.* Therefore, claim construction is an issue of law, *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). The Court’s construction becomes the legally operative meaning of the disputed terms that governs further proceedings in the case. *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1377 (Fed. Cir. 2005).

Claim construction begins “with the words of the claim.” *Nystrom v. TREX Co., Inc.*, 424 F.3d 1136, 1142 (Fed. Cir. 2005). A patentee often uses words in a claim in the same way as those of ordinary skill in the relevant art; therefore, the words of a claim are ““generally given their ordinary and customary meaning.”” *Phillips*, 415 F.3d at 1312 (quoting *Vitronics Corp.v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Thus, “[t]he inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation.” *Id.* at 1313.

“The person of ordinary skill in the art views the claim term in the light of the entire intrinsic record.” *Nystrom*, 424 F.3d at 1142. Accordingly, the Court must read the claims “in

view of the specification, of which they are a part.”” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc). In addition, ““the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.”” *Phillips*, 415 F.3d at 1318. Thus, the Court considers that a person of ordinary skill in the art would consult the rest of the intrinsic record, including any surrounding claims, the drawings and the prosecution history, if it is in evidence. *Id.*; see also *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002). In reading the intrinsic evidence, a person of ordinary skill in the art would give consideration to whether the disputed term is a term commonly used in lay language, a technical term, or a term defined by the patentee. Importantly, ““the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.”” *Phillips*, 415 F.3d at 1314–15.

Although greater weight should always be given to the intrinsic evidence, claim construction is a fluid process in which the Court may consider a number of extrinsic sources of evidence, so long as they do not contradict the intrinsic evidence. See *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582-83 (Fed. Cir. 1996); *Phillips*, 415 F.3d at 1324. Extrinsic evidence, such as dictionaries or expert testimony, may be useful when considered in the context of the intrinsic evidence, *id.*, at 1319, but it cannot ““alter a claim construction dictated by a proper analysis of the intrinsic evidence,”” *On-Line Techs., Inc. v. Bodenseewerk Perkin-Elmer GmbH*, 386 F.3d 1133, 1139 (Fed. Cir. 2004).

In some cases, disputed claim language involves a commonly understood term that is readily apparent to the Court. In such a case, the Court considers that a person of ordinary skill in the art would give the term its widely accepted meaning, unless a specialized definition is stated in the patent specification or was stated by the patentee during prosecution of the patent. In articulating the widely accepted meaning of such a term, the Court may consult a general purpose dictionary. *Phillips*, 415 F.3d at 1314. If a disputed term is a technical term in the field of the invention, the Court considers that one of skill in the art would give the term its ordinary and customary meaning in that technical field, unless a specialized definition is stated in the specification or during prosecution of the patent. *Phillips*, 415 F.3d at 1314. In arriving at this definition, the Court may consult a technical art-specific dictionary or invite the parties to present testimony from experts in the field on the ordinary and customary definition of the technical term at the time of the invention. *Id.* Claim terms should generally be given their ordinary and customary meaning unless “1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” *Thorner v. Sony Computer Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012).

The Federal Circuit has cautioned against positing constructions that “contribute nothing but meaningless verbiage to the definition of the claimed invention.” *Harris Corp. v. Ixys Corp.*, 114 F.3d 1149, 1152 (Fed. Cir. 1997). When a phrase will be readily comprehensible to the finder of fact, the term or phrase requires no construction. “Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not

an obligatory exercise in redundancy.” *NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1311 (Fed. Cir. 2005) citing *United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997).

#### IV. DISPUTED CLAIM TERMS

##### A. “carrier oil”

Term	XYMOGEN’S Proposed Construction	Thorne’s Proposed Construction
“carrier oil”	an oil that carries CoQ10 molecules in the passive facilitated diffusion process across absorptive cells in the intestine.	A material that increases the volume of an individual dosage of CoQ10 delivered into the intestine of the human taking the present invention, which increases the overall surface area from which the CoQ10 can be absorbed.

XYMOGEN’s proposed construction of “carrier oil” simply seeks to specify what the oil is carrying and where the oil is carrying its cargo to. When the patent specification states that the “carrier oil acts as a transporter for CoQ10 molecules in the passive facilitated [sic] diffusion process across the adsorption cells,” the patent is specifying that the carrier oil carries CoQ10, and that it carries CoQ10 across the absorption<sup>1</sup> cells. (Ex. A, 3:1-3)

The process by which the CoQ10 moves across the absorption cell is called passive facilitated diffusion. XYMOGEN does not believe that the process by which the CoQ10 travels

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<sup>1</sup> Also known as absorptive cells. (See Ex. C, Molecular Biology of the Cell, at 1275-76)

across the absorption cell is in dispute and inclusion of the process in the claim construction adds context to the construction and will assist the jury in understanding the claim.<sup>2</sup>

By way of analogy, the absorptive cell can be viewed as a security checkpoint. On one side of the security checkpoint is the inside of the intestine containing all the materials ingested by a person. The other side of the security checkpoint is blood. Compared to the contents of the intestine, the blood is relatively pure and its contents are highly regulated. The absorptive cell, the checkpoint, is selective about the types of molecules it will let through the checkpoint and into the blood. As mentioned in patent specification, CoQ10 is not one of the molecules that the absorptive cell normally lets into the blood. (Ex. A, 3:3-4) In the analogy, the carrier oil is an transport vehicle that has clearance to pass through the checkpoint. The carrier oil then carries the CoQ10 through the checkpoint and unless the carrier oil is carrying the CoQ10, the CoQ10 does not enter.

The flaw in Thorne’s proposed construction of “carrier oil” is that it does not require the oil to carry anything. As such Thorne’s proposed construction seeks to read out the word “carrier” from the phrase “carrier oil.” *Enzo Biochem Inc. v. Applera Corp.*, 780 F.3d 1149, 1154 (Fed. Cir. 2015) (the District Court’s construction “read out” a claim phrase and impermissibly broadened the claim) ((citing *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (“Claims are interpreted with an eye toward giving effect to all terms in the claim.”))).

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<sup>2</sup> To the extent Thorne does dispute the process by which CoQ10 travels across the absorption cells, XYMOGEN is willing to modify its proposed construction to: an oil that carries CoQ10 molecules across adsorptive cells in the intestine.

Not only does Thorne's proposed construction seek to read out the word "carrier," Thorne's construction actually seeks to read out even the word "oil." Throne's proposed construction only requires that the carrier oil be "a material."

The fact that a carrier oil must be an oil is confirmed by the '888 patent file history. During prosecution, in an effort to argue that the Udel patent did not anticipate the '888 patent, the applicant argued that beeswax disclosed in the Udel patent "cannot serve as a carrier oil since it is a thick wax well known in the art for uses in solid, semi-solid, and suspension preparations." (Ex. D<sup>3</sup>, Response to Office action dated July 22, 2010 at 6) In a subsequent office action, the examiner disagreed with the applicant that "Bee's wax is not considered a carrier oil." (Ex. D, Final Rejection dated Dec 6, 2010 at 3-4) Instead, the examiner quoted two standard definitions of the word "oil" and stated that the beeswax of Udell is an oil:

#### **Response to Arguments**

The Applicant argues that Bee's wax is not considered a carrier oil. However references available to one of ordinary skill in the art do not agree with such an assessment. Merriam Webster online defines an oil as:

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<sup>3</sup> Exhibit D is an extract of the '888 patent file history, no. 11/744,439

any of numerous unctuous combustible substances that are liquid or can be liquefied easily on warming, are soluble in ether but not in water, and leave a greasy stain on paper or cloth

WordNet defines oil as:

oil (a slippery or viscous liquid or liquefiable substance not miscible with water)

LipidBank teaches that beeswax is "a non-crystalline oily solid" which is "soluble in ether...but insoluble in water". Therefore since Udel teaches that bee's wax is easily liquefiable by melting (col 3, line 10) and LipidBank teaches that it is soluble in ether while being insoluble in water, it would qualify as a oil to one of ordinary skill in the art.

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This interaction between the applicant and examiner demonstrate that both the applicants and the examiner understood that a carrier oil needs to be an oil and not just any "material." *Phillips*, 415 F.3d at 1318 ("the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be").

Instead of requiring an oil and requiring that the oil carry something, Thorne's proposed construction merely requires that the carrier oil "increases the volume of the individual dosage of CoQ10 delivered into the intestine." Thorne finds support for this proposed construction in the patent specification reproduced below.

CoQ10 molecules cannot be absorbed. The lipid carrier also increases the volume of an individual dosage of CoQ10 delivered into the intestines of the human taking the present invention, which increases the overall surface area from which the CoQ10 can be absorbed. In one embodiment, the carrier oil of 5

(Ex. A, 3:4-8)

The word “also” signals a tangential effect of including the carrier oil, e.g. the lipid carrier, in the formulation. The tangential effect is to increase to volume of the individual dosage. This is not surprising, but it is immaterial to the construction. Of course adding a carrier oil to the formulation will increase the volume of the dosage. But so would adding other substances that are not carrier oils. For example, adding a solvent also increases the volume of the dosage, but that does not make the solvent a carrier oil. Adding water would increase the volume, but does not make water a carrier oil. Indeed, any additional substance added to the formulation will generally increase the volume of the dosage but that does not mean that these additional substances will all be carrier oils, and the fact that adding any substance increases the volume is not a definition of the term.

Thorne’s proposed definition is overbroad because it includes any material that will increase the volume of the individual dosage (which consequently and inherently increases the overall surface area from which the CoQ10 can be absorbed.) For the above reasons, Thorne’s proposed construction must be rejected.

#### **B. “non-crystalline”**

<b>Term</b>	<b>XYMOGEN’S Proposed Construction</b>	<b>Thorne’s Proposed Construction</b>
“non-crystalline”	Lacking crystals	Lacking crystals visible by light microscope at magnifications of 640X.

XYMOGEN does not believe the term “non-crystalline” needs construction, but to the extent that the Court believes a construction is needed, XYMOGEN proposes the plain meaning

of the term: lacking crystals. The American Heritage Dictionary of the English Language (1981) defines “non-” as “Indicates not.” (Ex. E) Hence non-crystalline means not crystalline or lacking crystals.

Thorne’s proposed construction of “non-crystalline” restricts the definition to detecting crystals only by a certain technique, i.e. visible by light microscope at magnifications of 640X. While the specific technique in Thorne’s construction appears in the patent specification in the description of one embodiment (*see* Ex. A, 2:30-33), restricting the construction of non-crystalline to that technique is not consonant with the plain meaning of the word and with the file history. For example, if one were to find crystals at 700X magnification but not at 640X magnification, would that be “non-crystalline?” According to Thorne’s proposed construction, the answer would be yes, that is “non-crystalline,” despite the fact that there are crystals in the formulation.

The file history supports XYMOGEN’s proposed construction that non-crystalline means, as the word plainly indicates, an absence of any crystals. In a July 22, 2010 Rejection, the examiner rejected the claims as indefinite because independent claim 1 recited a “non-crystalline” composition but dependent claim 5 recited an “essentially crystal-free” composition. In reaching his conclusion, the examiner interpreted the term “non-crystalline” as an “absolute limitation barring crystals from the composition.” (Ex. D, Non-Final Rejection dated July 22, 2010, at 3) In a subsequent response to the Rejection, the applicant conceded the examiner’s point and cancelled the offending claim 5. (Ex. D, Response dated Sept 22, 2010 at 6) Indeed, in that same response, the applicant used the examiner’s construction of “non-crystalline” to argue

that the Udel patent was not anticipatory: “Ultimately, the Udel Patent does not disclose **a complete lack of crystals**, as claimed in the instant claims . . .” (*Id.* at 7) (emphasis added)

The applicant therefore understood the term “non-crystalline” to mean a complete lack of crystals. *Phillips*, 415 F.3d at 1318 (“the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.”) A complete lack of crystals is not the same as the construction Thorne is now proposing where a composition can be “non-crystalline” even if the composition in fact contains crystals.

## V. CONCLUSION

Patents and their file histories serve an important public notice function. In exchange for a limited monopoly, the patentee claims a clearly defined invention. To allow the patentee to later broaden that invention subverts the very foundation of the Constitutional bargain. The inventors of the ‘888 patent claimed a carrier oil to carry CoQ10 across the intestinal wall. It is an oil that carries CoQ10--not merely a “material” that increases volume. And to overcome prior art, they conceded that crystal-free as used in the claims means a complete lack of crystals--not merely that no crystals can be found at 640x or under visible light. They cannot now broaden the claims in the *Markman* process to sweep in ground they gave up to obtain their patent.

XYMOGEN’s proposed constructions are supported by both the plain and customary meaning of these terms as they would be understood by a person of ordinary skill in the art, and comport with the well-established principles of law that govern claim construction. XYMOGEN respectfully requests that the Court adopt its claim constructions, as set forth above.

DATED this 15<sup>th</sup> day of May, 2015.

RAY QUINNEY & NEBEKER P.C.

/s/ Arthur B. Berger

James S. Jardine  
Arthur B. Berger  
Samuel C. Straight

K&L GATES LLP

L. Scott Oliver  
Ranjini Acharya

Attorneys for Defendant and Counterclaimant  
ATLANTIC PRO-NUTRIENTS, INC.,  
D/B/A XYMOGEN

**CERTIFICATE OF SERVICE**

I hereby certify that on the 15<sup>th</sup> day of May, 2015, I electronically filed the foregoing  
**ATLANTIC PRO-NUTRIENTS, INC., D/B/A XYMOGEN'S OPENING CLAIM**  
**CONSTRUCTION BRIEF** with the Clerk of the Court using the CM/ECF system, which sent  
notification of such filing to the following:

Kristine E. Johnson  
Juliette P. White  
PARSONS BEHLE & LATIMER  
201 South Main, Suite 1800  
Salt Lake City, Utah 84111  
[kjohnson@parsonsbehle.com](mailto:kjohnson@parsonsbehle.com)  
[jwhite@parsonbehle.com](mailto:jwhite@parsonbehle.com)

/s/ Lori M. McGee

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